Exhibit 11

Case: 1:17-md-02804-DAP Doc #: 1913-14 Filed: 07/19/19 2 of 7. PageID #: 89894

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

This document relates to:

Case No. 17-md-2804

Hon. Dan Aaron Polster

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.

Case No. 18-op-45090

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.

Case No. 17-op-45004

Expert Report of Jonathan Ketcham, PhD

May 10, 2019

alleged actions. As such, his claims that Defendants' conduct "result[ed]" in the illicit opioid mortality and misuse are misleading.³³⁶

X. Professor Gruber's Analysis Claiming that Shipments of Opioid Prescriptions Are Associated with Higher Crime Is Flawed

- 174. Professor Gruber claims to perform a brief review of the linkage between prescription opioids shipments and crime and then concludes that "shipments of prescription opioids are also associated with higher crime." Professor Gruber also speculates that "opioid misuse is also likely to lead to increases in property crimes (e.g. theft) or violent crimes (e.g. assault or robbery). For example, people using opioids may commit property or violent crimes to finance opioid addiction or because opioid addiction leads people to behavior that they would not otherwise engage in." However, no evidence (anecdotal or otherwise) is provided to support this hypothesis. In fact, it is important to note that Professor Gruber's analysis merely purports to show association, not causation, and it is also possible that higher crime might be the cause of the higher volumes of prescription opioids. 339
- 175. Professor Gruber's finding may be an instance of omitted variable bias. For example, it could be that shipments are correlated with causal factors such as unemployment rates, income inequality, and education rates. Not controlling for any of these factors renders Professor Gruber's analysis simplistic, possibly even misleading, and unreliable.
- 176. Some evidence of the relationship between crime and various socioeconomic factors such as unemployment, urbanization, income inequality, and poverty is available in the academic literature. For example,

³³⁶ Gruber Report, ¶ 89.

³³⁷ Gruber Report, ¶ 19.

³³⁸ Gruber Report, ¶ 109.

³³⁹ For example, this could be because higher crime rates allow for higher diversion rates of opioids, leading to increased shipments, or because areas with higher crime have medical needs that call for higher shipments of prescription opioids.

- Raphael and Winter-Ebmer in their study on the effect of unemployment on crime find "significantly positive effects of unemployment on property crime." 340
- Glaeser and Sacerdote find in their paper that crime rates are higher in cities than in rural areas because of factors including lower probability of arrest and recognition, and the presence of more female-headed households.³⁴¹
- Fajnzylber et al.'s study that investigates the causality between income inequality and violent crime finds that income inequality has a significant and positive effect on violent crime.³⁴²
- Lochner and Moretti's study on the effects of education on incarceration find that high school education significantly reduces criminal activity, with the biggest impacts associated with assault, murder, and motor vehicle theft.³⁴³
- 177. Professor Gruber considered none of these factors.
- XI. Professor Rosenthal's Direct Approach Suffers from Multiple Flaws, Is Unreliable, and Is Not Capable of Establishing a Causal Relationship between Defendants' Alleged Promotion of Opioids and Opioid Shipments. It Also Cannot Establish a Causal Relationship between Teva and Actavis Generic Defendants' Alleged Promotion and Opioid Shipments
- 178. Professor Rosenthal purports to "quantify directly the causal relationship between promotion and sales" by using what she calls "the direct approach."³⁴⁴ In this section I first give an overview of her methodology and then I explain why it is not capable of establishing a causal relationship between the Defendants' promotion of opioids and opioid shipments.
- 179. To illustrate the unreliability of the direct approach in drawing causal inferences about the effects of promotion, I first rely on well-established model validation techniques based on

³⁴⁰ Steven Raphael and Rudolf Winter-Ebmer, "Identifying the Effect of Unemployment on Crime," *The Journal of Law and Economics* 44, no. 1, 2001, pp. 259–283 at p. 259.

³⁴¹ Edward L. Glaeser and Bruce Sacerdote, "Why Is There More Crime in Cities?" *Journal of Political Economy* 107, no. S6, 1999, pp. S225-S258 at p. S225.

³⁴² Pablo Fajnzylber et al., "Inequality and Violent Crime," *The Journal of Law and Economics* 45, no. 1, 2002, pp. 1-40.

³⁴³ Lance Lochner and Enrico Moretti, "The Effect of Education on Crime: Evidence from Prison Inmates, Arrests, and Self-Reports," NBER Working Paper No. 8605, November 2001.

³⁴⁴ Rosenthal Report, ¶ 10.

"placebo tests." Specifically, her logic, model, and interpretation can be used to show the following: 1) that random numbers cause opioid shipments to virtually the same extent as opioid detailing; 2) that opioid detailing has a causal effect on the price of gold; and 3) that virtually all of the opioid shipments for the period 2003–2018 were caused by detailing prior to March 2002 alone. These spurious relationships demonstrate the unreliability and lack of usefulness of Professor Rosenthal's direct approach to establish a causal relationship between Defendants' alleged promotion of opioids and opioid shipments.

- 180. An important flaw in Professor Rosenthal's model is her use of a negative depreciation rate. After discussing the problematic nature of such a depreciation rate, I show that the use of depreciation rates that are more consistent with the academic literature yields results that directly contradict Professor Rosenthal's conclusions.
- 181. Finally, I describe a variety of other methodological flaws with the direct approach.

A. Overview of Professor Rosenthal's Direct Approach

- 182. In the econometric approach she terms the "direct approach," Professor Rosenthal attempts to quantify the effect of promotion on total shipments of opioids. The specific technique that she uses is a time series regression analysis and she asserts that such a technique captures "a dynamic causal relationship."³⁴⁵
- 183. The unit of observation in this regression is a month, aggregated across the entire U.S and across all opioid drugs.³⁴⁶ That is, the dependent variable used in this regression analysis is the number of morphine milligram equivalents ("MMEs") of all drugs (across all manufacturers) sold in the entire U.S. in a given month.³⁴⁷ In other words, Professor Rosenthal aggregates opioid drugs and geographies, and does not conduct the analysis at the manufacturer, drug, physician, or county level. The sample period ranges from January 1993–May 2018.³⁴⁸
- 184. Professor Rosenthal includes just two explanatory variables in her preferred specification: a measure of marketing based on the number of detailing contacts (i.e., the number of visits by

³⁴⁵ Rosenthal Report, ¶ 58.

³⁴⁶ Rosenthal Report, ¶ 58.

³⁴⁷ Rosenthal Report, ¶ 59.

³⁴⁸ Rosenthal Report, Table 1.

sales representatives to physicians' offices) and a price index.³⁴⁹ The monthly number of detailing contacts ("flow") is not the variable used in the regression, however. Professor Rosenthal instead uses the "detailing stock," which is equal to the detailing flow in that month plus the detailing stock in the previous month discounted by δ , the depreciation rate. 350 Professor Rosenthal estimates three different models.³⁵¹ Model A is a regression based on the detailing stock and the price index, as described above. The regression jointly estimates the coefficients for the explanatory variables and the value of δ . According to Professor Rosenthal, she develops a second model (Model B) because of alleged changes in prescribing attitudes and guidelines during the period she uses to conduct the regression analysis.³⁵³ She identifies three sub-periods—one until March 2002, another through July 2010, and a third starting in August 2010—but does not use the same specification for each one, and provides no explanation for this inconsistency.³⁵⁴ She uses the same intercept and coefficient on the price index throughout the period of her regression. The coefficient on the stock of marketing during the first sub-period is β_1 ; this coefficient during the second sub-period is β_2 . For the third subperiod, from August 2010 onwards, which covers the decline in opioids shipments, Professor Rosenthal changes her approach: the coefficient on the stock of marketing changes every month instead of being the same during this sub-period. To do so, she introduces a new parameter, β_3 , which represents the amount by which the coefficient on the stock of marketing decreases every month. For example, August 2010 is the first month of the third sub-period and the coefficient for this month is $\beta_2 + \beta_3 * 1$, or approximately 1103.355 Similarly, the coefficient for September 2010–the second month in the third sub-period–is $\beta_2 + \beta_3 * 2$ or approximately 1095. The coefficient for May 2018, the 94th month in the third sub-period, is $\beta_2 + \beta_3 * 94$ or approximately 362.356 In essence, the coefficient on the stock of marketing linearly decreases over time during the third sub-period. She also develops a third model, Model C, but concludes

³⁴⁹ Rosenthal Report, ¶ 60.

 $^{^{350}}$ Rosenthal Report, \P 62.

³⁵¹ Rosenthal Report, Table 1.

³⁵² Rosenthal Report, Table 1.

³⁵³ Rosenthal Report, ¶ 71.

³⁵⁴ Rosenthal Report, ¶ 71.

³⁵⁵ Author's own calculations, based on code that generates results in Rosenthal Report, Table 1.

³⁵⁶ The result differs from 1111-8*94 because 1,111 and 8 are rounded.